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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,477	01/23/2002	F.C. Thomas Allnutt	031676.0208	9546

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/937,477	ALLNUTT ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's amendment filed on 1/21/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-20 are pending.
2. Currently claims 1-13 are under examination. Claims 14-20 are withdrawn from further consideration.

### ***Election/Restrictions***

Applicant argues that the common technical feature of the claims is an assay based on the detection of the DHA-protein complex, not the protein that specifically binds to the DHA. Therefore, group I-III should be rejoined for examination. Applicant's argument has been considered but is not persuasive. The instant invention indeed depends on this special technical feature, namely DHA-specific protein to link the three group of invention, such as group I depending on this DHA-specific protein to bind to the DHA to determine the amount and presence of the DHA in a test sample, group II directs to a kit using this DHA-specific protein to detect the DHA, and group III directs to a recombinant fusion protein recognizing the DHA. Accordingly, the instant invention, as a whole, lacks unity of inventive concept under 37 CFR 1.475 based on the teachings Xu's reference where Xu et al. also use this DHA specific protein to detect the DHA binding affinity (J Biol Chem. 1996 Vol. 271, page 24711).

Thus the restriction requirement is deemed proper and Final.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al..

Xu et al. disclose a method of detecting a DHA sample by using its recognizing protein, i.e. brain lipid-binding protein (BLBP). The BLBP is a brain-specific member of the fatty acid binding protein involving the developing central nervous system (See left column, first paragraph). Xu et al. teach contacting the DHA samples with the BLBP protein (See page 24712, left column, Methods and Materials). The BLBP has differential binding specificity for DHA over other fatty acids, such as oleic acid (OA), aracidonic acid (AA), or eicosanoic acid. In particular, DHA possesses higher affinity than those fatty acids (See Table I). Xu et al. teach detecting the DHA-protein (BLBP) complex (See See page 24712, left column, Methods and Materials). The binding of the DHA and BLBP is an inherent indication of the presence of DHA.

With respect to claim 5, Xu et al. label fatty acid, e.g.  $H^3$ , as a detecting means to measure the binding between the fatty acid and BLBP protein (See Figure 2 and 3 and Table 1).

With respect to claim 6, Xu et al. found out that there is a 20-fold increase in affinity of BLBP for DHA compared to OA or AA (See Table I for the  $K_d$  values; and page 24717, right column, third paragraph).

With respect to claim 8, Xu et al. teach using a recombinant BLBP immobilized in a Lipidex 1000 column for fatty acid binding assay (See Methods and Materials).

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***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Ullman et al. (US 6326159).

Xu et al. reference has been discussed but is silent in using a protein, i.e. antibody to detect the DHA-BLBP complex or immobilized protein for detection. Ullman et al. review a method of producing an antibody recognizing a complex formed by a target ligand bound with ligand binding partner protein and immobilized protein on a solid support is commonly used in the art (Col. 5, line 30-45; Abstract; Example 8). Ullman et al. indicate that using a second antibody specifically for the complex of ligand with ligand protein can enhance specificity of binding results (See Col. 17, line 45-60). The technique of making the antibody involves routine skilled in the art. Supra. Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have provided Xu et al. with the antibody specific for recognizing the complex of the BLBP and DHA for enhance specificity.

4. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al.

Xu et al reference has been discussed but is silent in using biological samples in the analysis. However, Xu et al. review the role of BLBP in the developing central nervous system, including cell differentiation, signal transduction, and regulatory upregulation (See Introduction). Xu et al. also disclose the DHA molecule, biological cellular membrane lipid, has a high specificity and affinity for the BLBP. Therefore, it would have been obvious to one skilled in the art at the time when invention was made to apply the method of binding between BLBP and DHA in a biological sample, such as neural tissues, with reasonable expectation of success because the target ligand DHA for BHA is known, and understanding the development processes is of great interest in research field, and biological sample preparation involves merely routine practice in the art.

5. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Adams et al. (US 5447957).

Xu et al. reference has been discussed but is silent in teaching using hydrolyzing agent to release DHA from lipids for analysis.

Adams et al. teach using KOH, a non-enzymatic agent, to release fatty acid from lipid complex, for identification and quantitation (Col. 28, line 1-10). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Xu et al. with the KOH agent to release the target DHA from the lipid complex of the samples for better purity and detection efficiency.

***Response to Applicant's Arguments***

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*Xu's reference*

Applicant argues that Xu et al. does not teach every element recited, particularly Xu et al. teach a binding affinity study not using the BLBP to detect the presence or amount of the DHA in the instant. Instead, Xu et al. reference teaches determining whether and to what degree (i.e. the binding parameters) DHA would bind to BLBP. Applicant's arguments have been considered but are not persuasive. With respect to claim 1, examiner indicates that the *sample of DHA* is contacted with the protein, i.e. BLBP, for detection of the complex (DHA-BLBP)(emphasis added). The elements of claim 1 are embraced by Xu's teachings because the Xu's reference specifically teach using a protein (BLBP) having differential binding specificity for DHA over other fatty acids under conditions to measure a sample containing DHA, for the formation of the complex as indication of the presence of DHA.

*Conclusion*

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

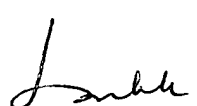
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner  
Art Unit 1641



March 24, 2005

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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04/07/05